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No. 94-572

IN THE
Supreme Court of the United States
OCTOBER TERM, 1994

DONNA E. SHALALA, SECRETARY OF HEALTH
AND HUMAN SERVICES,
Petitioner,
v.

MARGARET WHITECOTTON, *et al.*,
Respondents.

On Writ of Certiorari to the
United States Court of Appeals
for the Federal Circuit

DISSATISFIED PARENTS TOGETHER,
UNITED CEREBRAL PALSY ASSOCIATION,
NATIONAL TUBEROUS SCLEROSIS ASSOCIATION,
AND CENTER ON DISABILITY AND HEALTH,
AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*

Dissatisfied Parents Together is a non-profit nationwide organization of parents concerned about vaccine safety. Many of our members are the parents of individuals who have been injured or killed by vaccines.

Dissatisfied Parents Together participated prominently in the development of the National Childhood Vaccine Injury Act, and has remained deeply involved in the implementation of the National Vaccine Injury Compensation Program created by the Act.

United Cerebral Palsy Association is a confederation representing 152 state and local affiliates providing services to and advocating on behalf of 500,000 children and adults with cerebral palsy and their families. As part of our mission to improve the quality of life for persons with cerebral palsy, and others with severe disabilities, we promote personal health, home and public safety; influence the passage of laws and the allocation of public and private resources; and advocate for the development of family support systems that can nurture and provide for the needs of all family members including the family member with a disability.

The National Tuberos Sclerosis Association is a non-profit organization that provides support and advocacy for individuals with tuberous sclerosis and their families. Although tuberous sclerosis is present from birth, children with tuberous sclerosis are developmentally normal unless they develop seizures. Some children with tuberous sclerosis have their first seizures within a few days of a vaccination. The decision of the court of appeals correctly affords the statutory presumption to such children.

The Center on Disability and Health is a non-profit organization which serves as a resource to the disability community for conducting research, providing technical assistance, developing educational materials, and promoting health care reform from a disability prospective.

We believe that the court of appeals correctly decided the issue of when a child is entitled to the presumption of entitlement. We believe the standards for which the Secretary of Health and Human Services argues would defeat this central feature of the Program and deny compensation to many vaccine injured individuals.

SUMMARY OF ARGUMENT

The National Childhood Vaccine Injury Act provides a presumption that an individual who satisfies the conditions of the Vaccine Injury Table will be compensated.

This presumption greatly simplifies the determination of entitlement to compensation, and thereby, creates the relative simplicity, certainty and generosity which Congress intended the compensation program it created to provide.

The court of appeal's decision correctly afforded the presumption to a young woman who was healthy and developmentally normal until six hours after her third DTP vaccination. As *Amici Curiae* in support of Respondents, we urge the Court to affirm.

We also urge the Court to affirm the court of appeal's decision that the presumption that an individual will be compensated cannot be defeated unless the Secretary of Health and Human Services can establish a specific, known, cause for the individual's illness.

ARGUMENT

I. THE NATIONAL CHILDHOOD VACCINE INJURY ACT PROVIDES A PRESUMPTION THAT AN INDIVIDUAL WHO SATISFIES THE CONDITIONS OF THE VACCINE INJURY TABLE WILL BE COMPENSATED UNLESS THE SECRETARY ESTABLISHES A KNOWN CAUSE FOR THE INDIVIDUAL'S CONDITION WHICH IS UNRELATED TO THE VACCINATION.

The statute establishes a presumption that an individual who satisfies the conditions of the Vaccine Injury Table should be compensated. Although many decisions refer to this presumption as a "presumption of causation", it is actually more.

The statute provides that an individual who demonstrates the matters required by 42 U.S.C. Sec. 300aa-11(c) "shall be compensated" unless it is proven that her condition "is due to factors unrelated to the administration of the vaccine." 42 U.S.C. Sec. 300aa-13(a)(1). In most cases the critical matter required by 42 U.S.C. Sec. 300aa-11(c) is satisfaction of the conditions of the

Vaccine Injury Table. Once this is established, this is presumed that the person will be compensated.

This is a legal presumption and cannot be defeated by evidence that the vaccine could not have caused the individual's condition. The only way to defeat the presumption is for the Secretary of Health and Human Services to establish that a known cause, unrelated to the vaccination, caused the individual's condition. The statute carefully limits this defense to known causes.

"For purposes of paragraph (42 U.S.C. 300aa-13 (a)(1)). The term "factors unrelated to the administration of the vaccine"—

- (A) Does not include any idiopathic, unexplained, unknown, hypothetical or undocumented cause, factor, injury, illness, or condition and
- (B) May, as documented by the Petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and perinatal anoxia) or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case have shown to have been the agent or agents principally responsible for causing the Petitioner's illness, disability, injury, condition, or death.

42 U.S.C. Sec. 300aa-13(a)(2).

This presumption is a key feature of the National Vaccine Injury Compensation Program. The legislative history of the Act makes no secret of the breadth of the presumption.

"The Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The committee further recognizes that the deeming of vaccine-relatedness adopted here may provide com-

pensation to some children whose illness is not, in fact, vaccine-related."

"The Vaccine Injury Table sets forth a list of vaccines, injuries, and time periods of initial onset of injuries. *If a listed injury is first made manifest within the time period specified in the Table following the administration of the vaccine listed in the Table, the injury is to be considered compensable (unless there is other evidence to the contrary, as described above in Section 2113).*"

H.R. Rep. 908, 99th Cong., 2d Sess., pt. 1 at 18-19, *reprinted in U.S. Code Cong. and Admin. News* 6344, 6359-6360 (Emphasis added).

The two overriding concerns which led to the enactment of the National Childhood Injury Act were: 1) the inadequacy of the tort system (uncertainty and expense for both injured individuals and vaccine manufacturers), and; 2) the instability and unpredictability of the childhood vaccine market (as a result of unpredictable liability expense). *Id.* at 7, *reprinted in U.S. Code Cong. and Admin. News* 6344, 6348. A broad presumption of compensability was essential to both these purposes.

"The Committee anticipates that the speed of the compensation program, the low transaction cost of the system, the no-fault nature of the required findings, and the relative certainty and generosity of the systems awards will divert a significant number of potential plaintiffs from litigation."

Id. at p. 13, *reprinted in U.S. Code Cong. and Admin. News* 6344, 6354.

The National Vaccine Injury Compensation Program offers a non-exclusive remedy. It shields vaccine manufacturers from liability, and thereby encourages stability and predictability to the childhood vaccine market by attracting injured individuals into the Program and by encouraging them to accept the compensation awarded

through the Program. Congress recognized that this could be accomplished only through a broad presumption that individuals who satisfied the conditions of the Vaccine Injury Table would be compensated.

II. AN INDIVIDUAL WHO ESTABLISHES THAT THE FIRST SYMPTOM OR MANIFESTATION OF ONSET OR SIGNIFICANT AGGRAVATION OF A CONDITION SET FORTH IN THE VACCINE INJURY TABLE WITHIN THE PERIOD SPECIFIED IN THE VACCINE INJURY TABLE BENEFITS FROM THE PRESUMPTION THAT SHE WILL BE COMPENSATED.

The central controversy before the Court is over what an individual must establish in order to benefit from the statutory presumption.

We have set out what we believe to be the correct analysis below. We have described the analysis separately for cases in which the presumption is premised upon the "onset" of a Table condition, and those in which the presumption is premised upon the "significant aggravation" of a Table condition.

Although the court of appeals decision addresses only the issue of "onset", the special master's decision is based upon errors in analyzing the conditions which establish the presumption in both "onset" and "aggravation" cases.

A. An Individual Does Not Suffer the First Symptom or Manifestation of an Encephalopathy Until She Suffers a Symptom or Manifestation of Impairment of the *Function* of the Brain.

The statute clearly defines what an individual alleging the onset of a Table condition in association with a vaccination must prove to benefit from the statutory presumption that she is entitled to compensation.

1. What must be established.

An individual is entitled to the presumption if she demonstrates by a preponderance of the evidence that she:

"Sustained . . . an illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine . . . and the first symptom or manifestation of the onset . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table."

42 U.S.C. Sec. 300aa-11(c)(1)(C).

The two elements which the individual must establish are:

1. She suffers from a table condition; and
2. The first symptom or manifestation of the table condition occurred within the post-vaccination period provided in the Vaccine Injury Table.

The conditions covered in the Vaccine Injury Table are defined in the "Qualifications and Aids to Interpretation" section of the Vaccine Injury Table. 42 U.S.C. Sec. 300aa-14(b). The definitions in this section are critical because *only* "the first symptom or manifestation of onset" of an *Table* condition within the specified period provides the individual with the presumption.

In a case premised upon a Table encephalopathy, an individual must demonstrate the onset of a "significant . . . impairment of function of the brain" within the time period specified by the Vaccine Injury Table. 42 U.S.C. 300aa-14(b)(3)(A).

2. Legal standard applied.

The facts of this case provide a good example of how the courts below should have applied the simple criteria in the statute.

Maggie Whitecotton was microcephalic, her head circumference was between the second and third percentile,

prior to her August 18, 1975 DTP vaccination. Maggie Whitecotton was healthy, developmentally and physically, until she received her August 18, 1975 DTP vaccination. Within six hours of receiving her August 18, 1975 DTP vaccination, Maggie Whitecotton suffered a series of seizures, within thirty-six hours she suffered a second series of seizures. The seizures Maggie Whitecotton suffered within thirty-six hours of her DTP vaccination were symptoms of an impairment of the function of her brain, an encephalopathy. Maggie Whitecotton's disabilities are sequelae of that encephalopathy.

Maggie Whitecotton's claim under the National Vaccine Injury Compensation Program is based upon the occurrence of a Table encephalopathy in association with her August 18, 1975 DTP vaccination. DTP vaccine is covered by the Vaccine Injury Table. An encephalopathy within three days of a DTP vaccination is "an illness, disability, injury, or condition" covered by the Vaccine Injury Table. 42 U.S.C. Sec. 300aa-14(a).

The covered condition "encephalopathy" is defined in the "Qualifications and Aid to Interpretation".

"(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of *function of the brain*. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent and unusual screaming, persistent inconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of evidence that an encephalop-

athy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 2111 of this title for vaccine-related injury or death it is not possible to determine the cause, by a preponderance of evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record."

42 U.S.C. Sec. 300aa-14(b)(3) (Emphasis added).

Maggie Whitecotton was clearly entitled to the presumption.

She suffers from a Table encephalopathy. All parties agree that Maggie Whitecotton suffered seizures, and suffers mental and physical disabilities which are symptoms of a "significant acquired abnormality of, or injury to, or impairment of function of the brain". See 42 U.S.C. Sec. 300aa-14(b)(3)(A).

Maggie Whitecotton's microcephaly had caused no impairment in the function of her brain, no observable problem in her health or development before her August 18 1975 DTP vaccination. The first symptoms of any "impairment of function of the brain", and therefore the Table encephalopathy were the seizures Maggie Whitecotton suffered within three days of her August 18, 1975 DTP vaccination.

The *only* encephalopathy relevant to the determination of Maggie Whitecotton's claim for compensation under the National Vaccine Injury Compensation Program is her "Table" encephalopathy. The occurrence of symptoms which do not satisfy the statute's definition of an encephalopathy prior to the vaccination does not effect her claim.

3. *Analysis of the decisions below.*

The special master's conclusion that microcephaly was the first symptom or manifestation of Maggie Whitecotton's Table encephalopathy is clearly wrong as a matter of law. A condition is a Table encephalopathy only if it impairs the "function of the brain", and microcephaly is not a measure of brain function. The court of appeals decision corrected this error, and should be affirmed.

B. An Individual Suffers A Significant Aggravation of a Vaccine Injury Table Condition if a Comparison of the Symptoms of the Condition Before the Vaccination and the Symptoms Which Occur Within the Time Period Provided in the Vaccine Injury Table Demonstrates a Marked Change for the Worse.

The statute also defines what an individual alleging the significant aggravation of a Table condition in association with a vaccination must prove to benefit from the statutory presumption that she is entitled to compensation.

1. *What must be established.*

An individual is entitled to the presumption if she demonstrates by a preponderance of the evidence that she:

"... had significantly aggravated an illness, disability, or condition set forth in the Vaccine Injury Table in association with the vaccine . . . and the first symptom or manifestation of . . . the significant aggravation . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table."

42 U.S.C. Sec. 300aa-11(c)(1)(C).

The statute defines "significant aggravation":

"The term "significant aggravation" means any change for the worse in a pre-existing condition

which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health."

42 U.S.C. Sec. 300aa-33(d).

The two elements which the individual must establish are:

1. She suffered from a Table condition prior to the vaccination; and
2. There was a change for the worse in the Table condition in the post-vaccination period provided in the Vaccine Injury Table.

The change must result in "markedly greater disability, pain, or illness accompanied by substantial deterioration of health". 42 U.S.C. Sec. 300aa-33(d). This phrase is a measure of the significance of the change. It calls for a comparison of the observable symptoms before the vaccination and the observable symptoms within the time period after the vaccination prescribed by the Vaccine Injury Table.

The definition of "significant aggravation" does not require the individual to prove that the symptoms which occurred in the Table time period caused "markedly greater disability, pain, or illness" or that the changes observed in the Table time period would not have occurred had she not been vaccinated. Requiring such proof would be equivalent to requiring proof of causation in fact—precisely the proof the presumption is intended to make unnecessary.

2. *Application of legal standard.*

The legislative history provides an example of how the simple criteria of the statute should be applied.

"Significant aggravation" is defined below in Section 2133. The Committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in

the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g. a child with monthly seizures who, after vaccination, has seizures on a daily basis). The Committee also intended that the time periods set forth in the Table apply to the significant aggravation in order for causation to be deemed to exist (e.g., a significant deterioration of a seizure disorder after DTP vaccination must first become manifest within three days of the vaccination).

H.R. Rep. 908, 99th Cong., 2d Sess., pt. 1, at 15-16, reprinted in U.S. Code Cong. and Admin. News, 6344, pp. 6356-6357.

3. *An analysis of the decisions below.*

The special master's significant aggravation analysis relied upon the Court of Federal Claims decision in *Misasi v. HHS*, 23 Cl.Ct. 322 (1991). The critical language in the *Misasi* reads:

"To evaluate whether an individual suffered a significant aggravation of a particular condition, it is necessary to (1) assess an individual's condition prior to the administration of the vaccine, i.e., evaluate the nature and extent of the individual's pre-existing condition, (2) assess the individual's current condition after the administration of the vaccine, (3) predict the individual's condition had the vaccine not been administered, and (4) compare the individual's current condition with the predicted condition had the vaccine not been administered."

23 Cl.Ct. at 324.

The special master's decision focused upon elements 3 and 4 in the *Misasi* decision's analysis concluding:

"Maggie was born with a brain defect, and there was nothing that occurred in temporal relationship to the DPT vaccination which indicates that it is more likely than not that the vaccine permanently aggravated her condition."

J. App. p. 42a. The special master's findings of fact demonstrate the same analysis:

"5. No significant aggravation of Maggie's *brain* disorder was manifest within three days following the said administration of the DPT vaccine.

"6. The DPT vaccine did not cause a significant aggravation of Maggie's *condition*."

J. App. p. 42a.

The special master's analysis was clearly wrong. His focus was on a comparison of what Maggie Whitecotton's condition would have been had she not been vaccinated, and whether the DPT vaccination *caused* a significant aggravation of Maggie's condition. This analysis denied Maggie Whitecotton the statutory presumption and required her to prove causation in fact.

Recent decisions have uniformly held that steps 3 and 4 of the *Misasi* analysis apply *only* after the Secretary has established that the change in the child's Table condition was caused by a known factor unrelated to the vaccination. *Reusser v. HHS*, 28 Fed. Cl. 516 (1993); *Schumacher v. HHS*, 26 Cl.Ct. 1033 (1992), *aff'd* 2 F.3d 1128 (Fed. Cir. 1993). The special master erroneously applied steps 3 and 4 of the analysis without reaching the "factors unrelated" defense.

Since it is usually impossible to predict the course of a neurologic disorder, the special master's application of the *Misasi* standard abrogated Congress's intent to provide a presumption in cases in which a child suffered a change for the worse in a pre-existing Table condition following a vaccination.

The court of appeals did not reach the issue of pre-existing condition because it correctly concluded that Maggie Whitecotton was entitled to the presumption of entitlement on the basis of the onset of her Table encephalopathy.

III. A "FACTOR UNRELATED TO THE VACCINATION" CAN BE ESTABLISHED ONLY BY ESTABLISHING A KNOWN, IDENTIFIABLE CAUSE FOR THE INDIVIDUAL'S CONDITION.

The court of appeals was clearly correct in its ruling that microcephaly of unknown origin cannot provide the basis for a "factor unrelated" defense. This is clear from the statute, 42 U.S.C. Sec. 300aa-13(a)(2), and from the precedent in the court of appeals.

The statute could hardly be clearer:

"Sec. 300aa-13. Determination of eligibility and compensation

"(a) General rule. (1) Compensation shall be awarded under the Program to a Petitioner if the special master or court finds on the record as a whole—

"(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 2111(c)(1) [42 U.S.C.S. Sec. 300aa-11(c)(1)], and

"(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

"The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

"(2) For purposes of paragraph (1), the term 'factors unrelated to the administration of the vaccine'—

"(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

"(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbance which have no known relation to the vaccine involved by which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition or death."

42 U.S.C. Sec. 300aa-13(a).

Congress employed three nearly identical terms, "idiopathic," "Unexplained", and "unknown" to avoid any confusion about the statute's intent to preclude a defense on the basis of a condition for which the cause was not known.

The court of appeal's precedent is equally clear. In *Koston v. HHS*, 974 F.2d 157 (Fed. Cir. 1992), the court held that unless the cause of an illness is known, it cannot provide the basis for the "factor unrelated" defense.

"Our task is purely on a statutory interpretation. Section 30011-13(a)(1)(B) of the Vaccine Act bars compensation if there is 'a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine.' Accepting that Jenna exhibits the symptoms of Rett Syndrome, the question boils down to whether Rett Syndrome is a factor unrelated to the DPT vaccine. Section 300aa-13(a)(2)(A) defines unrelated factors as not including 'any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition.' Since the word 'or' is used with both the adjectives (idiopathic, unexplained, unknown, or hypothetical) and the norms

(cause, factor, injury, illness, or condition), it is apparent that an unrelated factor is not an idiopathic illness, an unexplained illness, or an unknown cause. As Koston says, 'The statute is plain enough. An 'idiopathic' condition, or a condition with an 'unknown cause', is not a 'factor unrelated to the administration of the vaccine.'"

974 F.2d at 160.

Rett Syndrome is also present from birth, 974 F.2d at 160, so the *Koston* ruling resolved the issues raised by the Secretary in this case.

The rule in *Koston* is an important part of the expedited compensation program established by the National Childhood Vaccine Injury Act. The *Koston* court noted:

"By the plain words of the statute, we have an unknown cause and seizures occurring within three days, the period the Vaccine Injury Table sets for recovery. 42 U.S.C. Sec. 300aa-14. That is the end of our inquiry, although we are also satisfied that this interpretation is consonant with the purpose of the statutory scheme which envisions that awards be made 'quickly, easily, and with certainty and generosity,' H.R. Rep. No. 908, 99th Cong., 2d Sess. 3 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 6344, even if this results in compensation to some children whose illness is not, in fact, vaccine-related.' *Id.* at 18, 1986 U.S.C.C.A.N. at 6359. But even if we were to credit the Secretary's suggestion that Jenna's receipt of an unwarranted award would be an absurd result, we could only respond that we are interpreting the statute as Congress wrote it. Avoidance of absurdity, if such it be, is its responsibility, not ours. *Tennessee Valley Auth. v. Hill*, 437 U.S. 153, 194 (1978)."

974 F.2d at 161.

The court of appeals decision below is even clearer.

"Congress intended that vaccine awards be made 'quickly, easily, and with certainty and generosity.'

H.R. Rep. No. 908, 99th Cong., 2d Sess. 3 (1986), reprinted in 1986 U.S.C.C.A.N. 6287, 6344. This purpose would not be served by allowing the Secretary to avoid an award by offering 'speculative or hypothetical matter or explanations' of alternate causation; under the Act, a Table injury must be presumed vaccine-related unless demonstrated to arise from 'other' defined 'illnesses or factors.' *Id.* at 18, 1986 U.S.C.C.A. at 6359. This may result in 'compensation to some children whose illness is not, in fact, vaccine related,' *Koston*, 974 F.2d at 161 (citations omitted), but that is what Congress intended. As in *Koston*, 'we have an unknown cause and (symptoms) occurring within three days, the period the Vaccine Injury Table sets for recovery. That is the end of our inquiry. . . ' *Id.* The Whitecotts established their prima facie case, and so get benefit of presumptive causation."

17 F.3d 374, at 378.

Contrary to the Secretary's arguments, this rule leads to precisely the results Congress intended: relative simplicity, certainty, and generosity.

The court of appeals most recent decision in the area, *Knudsen v. HHS*, 35 F.3d 543 (Fed. Cir. 1994) also follows *Koston*. The court of appeals held that proof that a viral infection caused an encephalopathy can provide the basis for a factor unrelated defense. The court of appeals remanded the claim (which had been denied by the special master below) with instructions that the special master determine if the Secretary had proven that the child's encephalopathy was, in fact, caused by viral infection. 35 F.3d at 548-551.

The Secretary's criticism of *Koston* is premised upon the fundamental misconception of law which permeates this appeal: The Secretary's belief that the statute provides a presumption of causation only. This misconception leads the Secretary to believe that evidence that the vaccine did not cause a Table injury should defeat the presumption.

As we have explained above, the presumption is broader: that a person satisfying the conditions of the Vaccine Injury Table will be compensated. This legal presumption can be defeated only by the means recognized in the statute: by establishing a known cause for the child's condition which is unrelated to the vaccination.

IV. THE COURT OF APPEALS DECISION DOES NOT THREATEN THE FISCAL INTEGRITY OF THE PROGRAM.

The American Academy of Pediatrics, as *amicus curiae* in support of the Secretary, has argued that the court of appeals decision "threatens the fiscal integrity of" the National Vaccine Injury Compensation Program. That is nonsense. The decision does not "expand" the conditions under which an individual is entitled to compensation. It does not, therefore, impact the "fiscal integrity" of the Program.

The Program's current annual appropriation of \$110,000,000 is sufficient for cases arising from vaccinations administered prior to October 1, 1988, and there is a large surplus available in the trust fund for cases arising after October 1, 1988. Proceedings of the Advisory Commission on Childhood Vaccines, September 28, 1994, pp. 52-53. A measure of the weakness of this argument is the fact that the Secretary raised it in her Petition for Certiorari, but does not include it in her brief.

CONCLUSION

One of the central principles of the National Vaccine Injury Act is the broad presumption that persons satisfying the conditions of the Vaccine Injury Table will be compensated. The court of appeals honored that principle, correctly holding that: a healthy, developmentally normal child who developed symptoms of a Table encephalopathy within the time period specified in the Vaccine Injury Table was entitled to the presumption; and that a condition for which no cause can be established could not defeat the presumption. You should affirm the court of appeals decision.

Respectfully submitted,

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